

DRUGS FOR VETERINARY USE

6164. Cardiobee 15 injection and Cardiobee 15 solution. (F.D.C. No. 44256 S. Nos. 72-340/2 P.)

QUANTITY: 163 10-cc. vials and 71 30-cc. vials of *Cardiobee 15 injection* and 11 1-pt. btls. of *Cardiobee 15 solution* at Hialeah, Fla.

SHIPPED: 3-10-59 and 8-7-59, from San Francisco, Calif., by John Beard Memorial Foundation.

LABEL IN PART: (Vial) "Multiple Dose Sterile Vial Cardiobee 15 Injection Each 10 cc. contains 100 mg. of Na-Glucono-di (N-Diisopropylamino) Acetate Benzyl Alcohol .2% Physiological Saline Solution q.s. For Veterinary Use Only Dist. by—Zirin Enterprises, Hialeah, Florida" and "Cardiobee 15 Solution * * * For Oral Use Each ounce contains 50 mg. of Na-Glucono-Di (N-Diisopropylamino) Acetate Water q.s. For Veterinary Use Only * * * Distributed by Zirin Enterprises—Hialeah, Florida."

LIBELED: About 3-17-60, S. Dist. Fla.

CHARGE: 505(a)—the articles, when shipped, were new drugs which may not be introduced into interstate commerce since applications filed pursuant to law were not effective with respect to such drugs.

DISPOSITION: 6-17-60. Default—destruction.

DRUGS AND DEVICE ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

6165. Natural Formula 52 Sulphur Cream Lotion, Natural Formula 51 Sulphur Bath Concentrate, and Instant Sulphur Bath Concentrate. (F.D.C. No. 43942. S. Nos. 83-501/3 P.)

QUANTITY: 766 2-oz. btls. of Formula 52; 5 cases, 24 8-oz. btls. each, of Formula 51; and 10 cases, 24 8-oz. btls. each, of *Instant Sulphur Bath Concentrate*, at Oklahoma City, Okla.

SHIPPED: Between 1-19-59 and 2-9-59, and other unknown dates during 1958 and 1959, from Park Ridge, Ill., by Trenkmann Laboratories.

LABEL IN PART: (Btls.) "Natural Formula 52 Sulphur Cream Lotion Skin Supplement * * * Distributed by: K. V. Products Company * * * Oklahoma City 18, Oklahoma," "Natural Formula 51 Sulphur Bath Concentrate * * * Distributed by K. V. Products Company * * * Oklahoma City 18, Okla.," and "Instant Sulphur Bath Concentrate * * * Trenkmann Laboratories, Park Ridge, Illinois."

ACCOMPANYING LABELING: Leaflets entitled "At Last Science Discovers How To Put Natural Sulphur Into Perfect Solution!"

LIBELED: 12-30-59, W. Dist. Okla.

CHARGE: 502(a)—when shipped, the labeling of the articles contained false and misleading representations that the *Natural Formula 52 Sulphur Cream Lotion* contained sulfur which would completely penetrate and absorb into the skin; would keep the skin youthful; that it was hypo-allergenic; and that it replenished sulfur-hungry tissues and helped restore the sulfur balance of the skin; and that the *Natural Formula 51 Sulphur Bath Concentrate* and *Instant Sulphur Bath Concentrate* were an adequate and effective treatment for arthritis; rheumatism; lumbago; nervous fatigue; sore muscles; aching

*See also Nos. 6161, 6162.

joints; bursitis; acne; eczema; dermatitis; psoriasis; allergies; and that it would relieve itching and burning irritations on hands, arms, and body; and would maintain a youthful skin and keep one free of pain, healthy, and young; and 502(f) (2)—the labeling of the *Natural Formula 52 Sulphur Cream Lotion* failed to bear such adequate warnings against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users since the article contained sulfur and its labeling failed to warn that if undue skin irritation developed or increased, the use of the article should be discontinued and a physician consulted.

DISPOSITION: 2-10-60. Default—destruction.

6166. Mills Aloin, Cascara and Phenolphthalein Compound tablets. (F.D.C. No. 44402. S. No. 25-404 R.)

QUANTITY: 1 drum of 72,096 tablets at Reseda, Calif., in possession of Mills Pharmaceutical Co.

SHIPPED: 12-4-59, from Portland, Oreg., by Don Hall Laboratories.

LABEL IN PART: (Drum) "Tablets Mills Aloin, Cascara & Phenolphthalein Compound."

RESULTS OF INVESTIGATION: The tablets, after their receipt at Reseda, Calif., were to be repacked, in the normal course of the dealer's business operations, into bottles labeled in part "28 Tablets 11901 Control No. Mills Aloin, Cascara & Phenolphthalein Compound D-4 * * * Formula: Phenolphthalein 1 gr. Ext. Cascara $\frac{1}{2}$ gr. Pepsin 1-3000 $\frac{1}{2}$ gr. Aloin $\frac{1}{4}$ gr. Podophyllin $\frac{1}{8}$ gr. Diastase of Malt $\frac{1}{8}$ gr. Oleo Resin Ginger 1/100 gr. Directions: Adults * * * Children * * * Manufactured for Mills Pharmaceutical Co. Encino, California."

Examination showed that the article contained 1 grain of phenolphthalein, pepsin, aloin, and probably other plant extractive material.

LIBELED: 3-29-60, S. Dist. Calif.

CHARGE: 502(f)—the labeling of the article, when shipped and while held for sale, failed to bear (1) adequate directions for use and (2) a warning statement that use of the article should be discontinued when abdominal pain, nausea, vomiting, or other symptoms of appendicitis were present, that frequent or prolonged use of the article may result in dependence on laxatives, and that preparations containing phenolphthalein should not be used if a skin rash appeared.

DISPOSITION: 5-24-60. Consent—claimed by Mills Pharmaceutical Co. and relabeled.

6167. Hunt's 3-Minute Balm. (F.D.C. No. 44364. S. No. 88-146 P.)

QUANTITY: 504 2-oz. btls. at Morehead, Ky.

SHIPPED: On various dates between July 1959, and the week of 1-14-60, from Detroit, Mich., by Hunt Bros. Product Co.

LABEL IN PART: (Btl.) "Hunt Bros. Product Company 3-minute Balm * * * Active Ingredients: Menthol, Methyl Salicylate * * * Manufactured by Hunt Bros. Directions: Rub on affected parts."

ACCOMPANYING LABELING: Blue and yellow leaflets entitled "Hunt's 3-Minute Balm."

LIBELED: 3-8-60, E. Dist. Ky.